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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,918	09/15/2003	Sean B. Carroll	OPHD-08258	2733

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
07/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,918	CARROLL ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3-13 and 15-21 are pending and are under consideration.

2. In view of Appeal Brief filed on 1/15/09, PROSECUTION IS HEREBY REOPENED.
In view of applicants' arguments, the art rejections of record have been withdrawn and new grounds of art rejection are set forth. Claim 21 that was inadvertently left out of the rejections in the previous office action is included in the new grounds of rejection. A new matter rejection of claim 21 that was not of record in the previous office action has been added.

To avoid abandonment of the application, appellant must exercise one of the following two options:
(1) file a reply under 37 CFR 1.111 or a reply under 37 CFR 1.113; or
(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affadavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

The arguments presented by applicant as part of the brief filed January 15, 2009 all refer to specific prior rejections and the references found therein. As such, most of these arguments are moot. However, any arguments which are applicable to the new rejections set forth below will be addressed with the rejections.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

4. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification and the original claims as filed do not provide written description for the phrase "wherein said subject has not been treated to induce tolerance". Indeed, a text search of the document failed to uncover the words "tolerance", "tolerize" or "tolerization" in the text as filed. Claim 21 is not an original claim and is recited as being dependent upon claim 8, but applicant has not indicated where support for claim 21 is located. Given that neither the specification nor the original filed claims contain the word "tolerance" or reasonable variations thereof, it appears that applicant has introduced a new limitation to the claimed invention during the course of prosecution. Such an introduction of new limitations into the claimed invention which did not appear in the specification as filed introduces new concepts and thus violates the description requirement of the first paragraph of 35 U.S.C.112.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-13 and 15-21 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No.5,080,895, of record, in view of Barnes et al. (Journal of the American Veterinary Medical Association, 1964, vol.144, p. 1391-1394, newly cited).

It is noted that the independent claims broadly recite administering antibodies that bind *Clostridium perfringens* to a subject without any indication of the purpose or motivation behind such an administration. However, in view of dependent claims reciting "therapeutic" administration (such as claim 7) and in light of the specification (p. 6, lines 8-23, and Example 2(b), pp. 25-26), all pending claims for examination purposes have been examined as being methods of disease treatment.

The '895 patent teaches methods of treating and inhibiting the development of intestinal infectious diseases in neonatal mammals, such as piglets, by orally administering antigen-specific antibodies obtained from the eggs of immunized hens (see entire document, particularly the abstract, the paragraph spanning columns 3 and 4, and claims 1-11). Antibodies thus obtained have the advantages of being produced inexpensively at any time of the year, as well as being suitable for oral administration (from line 30 of column 3 to line 4 of column 4). It is disclosed that the specific antibody is prepared by immunization of a hen with a selected antigen, and that preferred antigens are obtained from pathogenic bacteria or other factors which cause intestinal infectious diseases in animals (col. 3, lines 35-40 and col. 4, lines 50-61). The '895 patent also provides working examples demonstrating that orally administered antibodies are beneficial in the treatment and inhibition of intestinal infections, particularly bacterially induced diarrhea in young piglets (paragraph overlapping columns 4-5 and Example III).

Further, the '895 patent teaches that the specific antibody is administered in solution form and is to be used as a nutritional supplement or food additive (col. 7-8). Also, Example III beginning in column 10 discloses a working example wherein antibodies specific for *E. coli* were administered in a solution of artificial milk to newborn

piglets. Thus the prior art discloses the use of avian antigen specific antibodies in infant formula. These piglets were then challenged with *E. coli* and it was observed that they had lower incidences of diarrhea, recoverable infectious bacteria in their stool, and death as compared to control piglets which had not been administered the avian antigen specific antibody (see particularly Tables 2-4). Since the antibodies were administered prior to infection, the methods of the '895 patent are prophylactic, and since they decreased the severity of diarrhea they are also therapeutic (see also patented claims 1-11). Note that the piglets of Example III were administered avian antibody without prior exposure to avian antigens, and as such the piglets had not been pretreated to induce tolerance, a limitation of claim 21 of the instant application. This aspect of the methods of the '895 patent is also explicitly disclosed in lines 34-36 of column 8, which states "The administration to an animal can be performed at any time without the need for the animal to acquire resistance to ovular antibodies".

The teachings of the '895 patent differ from the claimed invention in that the patent does not disclose *C. perfringens* as a pathogen to which avian antibodies are made and administered to neonatal animals, such as piglets.

Barnes et al disclose that *C. perfringens* causes intestinal infections in piglets in various countries and that administering antibodies which react with *C. perfringens* has been demonstrated to reduce mortality in newborn pigs under 3 weeks old (see entire document, particularly the second paragraph of the left column of page 1391).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute *C. perfringens* for the pathogenic bacteria used in the methods of the '895 patent. Motivation to do so comes from the fact that the methods of the '895 patent are disclosed for use with any pathogenic species of bacteria and *C. perfringens* is a known intestinal pathogen of piglets as is disclosed by Barnes et al. An ordinary artisan would have a reasonable expectation of success in orally administering avian anti- *C. perfringens* antibodies to piglets since as per Barnes et al. it was known in that art that administering anti- *C. perfringens* antibodies was therapeutically useful and that oral administration of avian antibodies specific for bacterial pathogens was therapeutically useful as per the disclosure of the '895 patent.

A person of ordinary skill in the art would have been further motivated to use avian antibodies since they have the advantages of being able to be produced year round in an inexpensive manner.

Applicant has argued that the prior art teaches a requirement that the subject of the performed method be previously exposed to avian antigens to effect tolerance in said subject, and that such a requirement teaches away from the claimed invention.

This argument is not persuasive, because as the working examples of the '895 patent clearly demonstrate, no prior exposure to avian antigens is required prior to being administered an avian antibody.

Applicant has also argued that the prior art uses monoclonal antibodies and discloses the advantages of using monoclonal antibodies as compared to polyclonal antibodies. Thus applicant asserts that a person of ordinary skill in the art would have been led away from using polyclonal antibodies, such as the avian IgY used in the instant claimed methods.

This argument is not persuasive because the '895 patent discloses the successful use of polyclonal avian antibodies and their advantages which include their ability to be made cheaply year round. Further, the Barnes et al. reference is from 1964, many years prior to the advent of monoclonal antibody technology, and thus anti-*C. perfringens* antibodies discussed therein are necessarily polyclonal. Thus a person of ordinary skill in the art would expect administration of a polyclonal avian antibody to be therapeutically useful.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F, 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can

be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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